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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,074	08/02/2000	Geoffrey Charles Nicholson	DAV1103.001AUS	9705

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EXAMINER
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SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/12/2003

*20*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/632,074**

Applicant(s)  
**NICHOLSON**

Examiner  
**Christine Saoud**

Art Unit  
**1647**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 2, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-10 and 13-19 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment of 02 June 2003 is noted and entered into the instant application. Upon review of the pending claims in light of the amendment to the sequence identifiers, it has become apparent that the claims as currently grouped encompass multiple inventions. Therefore, a new restriction requirement is being issued. The delay in prosecution that this new restriction presents is regretted, but hopefully will advance prosecution.

In reviewing the claims, a problem in the claim language has been discovered. The claims are indefinite, and therefore, some claims may or may not belong to the specified groups. Furthermore, additional groups may be required depending on what Applicant is intending to claim. Claim 6 requires administration of leptin, or a derivative, homologue, analogue, chemical equivalent or agonist thereof. However, claim 7 further recites "antagonist", which is not recited in claim 6. The fact that claim 6 is directed to inhibition of bone resorption by administration of leptin or an agonist of leptin, calls into question a method of inhibition of bone resorption by administration of an antagonist. An antagonist should do the opposite of the actual compound (i.e. leptin), so the inclusion of this compound in claim 7 may be a typographical error, or may require an additional inventive group. This same discrepancy is found in claims 13 and 14. Applicant should correct this problem in the next response in addition to electing an invention for examination.

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Applicant's election of Group I in paper #19 is noted, but moot in light of the new restriction requirement below.

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 17-18, drawn to a method of reducing bone resorption by administration of leptin (or derivative, homologue, analogue, chemical equivalent), classified in at least class 514, subclass 12, for example.
  - II. Claims 1-9 and 17-18, drawn to a method of reducing bone resorption by administration of an agonist of leptin, classified in class undetermined, subclass undetermined (as no structure is provided for the agonist).
  - III. Claims 1-3 and 17, drawn to a method of increasing bone resorption by administration of an antagonist of leptin, classified in class undetermined, subclass undetermined (as no structure is provided for the antagonist).
  - IV. Claim 10, drawn to a composition comprising leptin, classified in class 514, subclass 2, for example.
  - V. Claims 13-16 and 19, drawn to a method of inhibiting osteoclastogenesis by administration of leptin (or derivative, homologue, analogue, chemical equivalent), classified in at least class 514, subclass 12.

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VI. Claims 13-16 and 19, drawn to a method of inhibiting osteoclastogenesis by administration of an agonist of leptin, classified in class undetermined, subclass undetermined (as no structure is provided for the agonist).

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions (I-III, V-VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct methods (i.e. increasing bone resorption, decreasing bone resorption, inhibiting osteoclastogenesis) which have distinct goals and methods with different starting materials (leptin and related compounds versus agonists of leptin versus antagonists of leptin). The inventions are directed to methods that are distinct both physically (requiring administration of different agents) and functionally (requiring different outcomes), and are not required one for the other.

4. Inventions IV and (I,V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the invention of Group IV could be used in an entirely different process, such as in a method of treating obesity, rather than in the methods of Groups I or V.

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5. Inventions IV and (II-III, VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the inventions of Groups (II-III, VI) require the administration of agonists or antagonists of leptin, which are distinct compounds from the leptin compounds in Group IV.

6. The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches. The methods have different goals, method steps and/or starting materials. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*